I-Bresis™ Patch Carton Contents:

- 6 Patches
- 6 Saline Ampoules
- 6 Alcohol Preps

READ THE I-BRESIS™ CONTROLLER AND CHARGING STATION INSTRUCTIONS FOR USE FOR ADDITIONAL IMPORTANT INFORMATION.
Keep Away from Sunlight

Medical Equipment Classified by Underwriters Laboratories Inc., with respect to electric shock, fire and mechanical hazards only in accordance with UL-60601-1, and CAN/CSA C22.2 No. 601.1-M90.

Storage: 15°C - 30°C (59°F - 86°F)

DO NOT expose to temperatures above 50°C (122°F)

Consult Instructions

For Prescription Only
Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

DO NOT REUSE patches that have been previously used as these patches have been designed for single use only. Reuse may cause burns to patient.

Precautionary Instructions

Non-sterile

Type BF Applied Part

Keep Dry


Not Made With Natural Rubber Latex
INDICATIONS

The I-Bresis™ System is indicated for the administration of soluble salts or other drugs into the body for medical purposes as an alternative to hypodermic injection.

FOR ADDITIONAL IMPORTANT INFORMATION, READ THE I-Bresis™ CONTROLLER AND CHARGING STATION INSTRUCTIONS FOR USE.

CONTRAINDICATIONS

- **Implanted Electronic Devices** - Do not use this device on patients who have a cardiac pacemaker, implanted defibrillator, or other implanted electronic device, because this may cause electric shock, burns, electrical interference, or death.

- **Drug sensitivity** – Do not use on patients with known sensitivity to the drug being administered.

- **Pregnancy** – Do not use on pregnant women. The safety of the system used during pregnancy has not been established.

- **Scarring** – Do not use on damaged skin, denuded skin or other recent scar tissue.

- **Skin sensitivity** – Do not use on patients with known sensitivity to electrical current or to the solution being administered.

- **Head treatment** – Do not treat across either the temporal region or the orbital region.
• **Children** – Keep out of the reach of children.

• **Across Chest** – Do not apply stimulation across the patient’s chest, because the introduction of electrical current into the chest may cause rhythm disturbances to the patient’s heart, which could be lethal.

• **Across Head** – Do not apply stimulation across the patient’s brain, as safety has not been established.

• **Pain** – Advise the patient to remove electrodes if any undue sensation of pain or burning occurs during the treatment and to report discomfort to clinic.

• **Skin Condition** – To establish good contact between the electrodes and skin, excessive hair may be clipped, but DO NOT SHAVE. Shaving may cause skin breaks that are not readily seen and can increase the risk of adverse skin reactions. Do not apply over broken or compromised skin (e.g., sunburns, cuts, or acne) due to increased risk of skin reaction.

• **Blisters** – Small pinhead size blisters may result in response to certain drugs. Contact physician if problem persists longer than 24 hours.

• **Skin Reactions** – On rare occasions, iontophoresis therapy can result in transient skin reactions such as rash, inflammation and irritation. These skin reactions may be the result of individual sensitivity to the ionic solution used, the condition of the skin at the onset of treatment, reaction to the materials in the electrodes, or a poor connection between the electrode and the patient’s skin. Advise the patient of this possibility before starting treatment. If a visible skin reaction does occur, instruct the patient to discontinue the treatment and consult the prescribing physician.

• **Electromagnetic Interference** – Care must be taken when operating this equipment adjacent to or stacked with other equipment. Potential electromagnetic or other interference could occur to this or to the other equipment. Care should be taken to minimize this interference by not using other equipment in conjunction with it.

• **Flammable Anaesthetics** – The system is not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.

• **MRI** – Do not wear electrode or controller during Magnetic Resonance Imaging (MRI) scans as this may result in metal overheating and causing skin burns in the area of the patch.

• **No modification of this equipment is allowed.**

• **Potential systemic adverse effects may result from use of this device. Drugs or solutions delivered with this device have the potential to reach the blood stream and cause systemic effects. Carefully read all labeling of the drug or solution used with this device to understand all potential adverse effects and to ensure appropriate dosing information. If systemic manifestations occur, refer to the drug or solution labeling for appropriate action.**
**PRECAUTIONS**

- **Drug Information** – Consult directions for the use of the drug/compound before delivery. Some drugs/compounds require a specific polarization for use. Observe the indications, contraindications, warnings and precautions related to this issue.

- **Single Use** – Do not use electrodes that have been previously used. These patches have been designed for single use only. Reuse may cause burns to patient.

- **Packaging Information** – Inspect the electrode packaging before use. Do not use electrodes past the Best If Used By date printed on the packaging. Do not use electrodes if the packaging is not sealed. The electrodes may not be as effective if they are used past the Best If Used By Date or if they have been exposed to high humidity for an extended period of time.

- **Electrode Inspection** – Inspect the electrodes before use. Discard any electrode that shows signs of alteration or damage, as these electrodes may not be safe for use.

- **Excessive Motion** – The electrodes can be worn during normal activity. However, excessive motion where the electrodes have been placed can cause poor contact between the skin and the electrode or uneven distribution of current, resulting in greater risk of skin irritation.

- **Erythema** – A transient erythematous reaction, characterized by a uniform red pattern, can sometimes occur directly under the electrodes. The redness usually disappears within a few hours after treatment. Advise the patient of this possibility before starting treatment.

- **Positive Polarity with Chloride Ions** – Use only saline ampoule supplied for the return pad. For positive polarity (+), use only drugs with Chloride (Cl-) counter ions. Use of tap water or any other solution may cause tattooing or staining.

- **Handle with Care** – Handle the system with care. Do not immerse the system in fluids or allow it to be connected with other electrical devices. Do not drop, abuse, or in any way exceed normal use. Do not sterilize. Misuse may cause the device to malfunction in ways that may lead to shock or burns.

- **Use with RF Equipment** – Do not operate this system in an environment where other devices are being used that intentionally radiate electromagnetic energy in an unshielded manner. Portable and mobile RF communications equipment can affect Medical Electrical Equipment.
PATCH DESCRIPTION AND INTENDED USE

The I-Bresis™ Patch is a disposable, single-use Patch with an internal battery and current-limiting circuitry. It can deliver both negatively and positively charged water-soluble drugs/compounds across intact skin. The Patch can be used with and without the Controller. The Controller is used with the Patch to deliver an I-Bresis™ or Standard Treatment. A Patch-Only Treatment does not require the use of the Controller.

The Patch is an Applied Part that is intended to deliver energy and ions (charged atoms or molecules) across the patient’s skin. The Patch is a prescription device in the USA. The clinician is responsible for selecting the appropriate drug and treatment site for the condition being treated. The Patch is intended to be applied in a clinic or hospital setting by the clinician. I-Bresis™ and Standard Treatments that use the I-Bresis™ Controller are intended to occur in a clinic or hospital setting for the time that the Controller is attached to the Patch. The Patch itself is designed for home use. The Patient may wear the Patch out of the clinic for Patch-Only or I-Bresis™ Treatments. At the discretion of the clinician, Patches may also be sent home with the patient for future treatments.

Drug Polarity Labeling
The polarities of the drug pads are labeled on the Patch.

Patch Drug Pads
The Patch has two drug pads. Each drug pad has a ~1.5 ml fill volume. Use negatively charged water-soluble drugs/compounds on the negative (-) drug pad and positively charged water-soluble drugs/compounds on the positive (+) drug pad. For (+) polarity, use only drugs with Chloride (Cl-) Counter Ions.

Battery Pack and Controller Connector
The Battery Pack that contains two 3-Volt batteries is also the connecting location for the Controller.
THEORY OF OPERATION

The I-Bresis™ Iontophoresis System operates on the physical principle that electrically like-charges repel each other. A positively charged substance is forced away from a positively charged electrode. A negatively charged substance is forced away from a negatively charged electrode. When the Patch pads are filled with ionic saline or drug solutions and the Patch is attached to the patient’s skin, current begins flowing. The ionic solutions are forced into the skin away from the like-charged electrode. The dosage of ionic drug solution delivered depends on the current applied and the length of time for which the current is applied. Dosage is expressed in units of mA min (milliAmpere minutes) and is calculated by multiplying the current (mA) by the time (min).

PREPARING THE PATIENT

Advise the patient that iontophoresis has the potential to result in skin irritation and/or burns.

- Direct current may result in transient erythema under the pads. The erythema generally resolves itself within a few hours.
- Use caution when treating patients with sensitive skin or those who may have difficulty healing.

1. Advise the patient that iontophoresis causes mild tingling, prickling and/or a warm sensation. This is normal and should be anticipated by the patient.

2. Advise the patient to report immediately any pain during treatment. If the patient complains of pain, pause the treatment, inspect the area under the Patch and make any necessary adjustments (e.g., reposition the Patch to ensure full skin contact, decrease current, etc.) before resuming the treatment, or discontinue the treatment.

3. Advise the patient to remove any jewelry that may come in contact with the Patch.
PREPARING THE PATCH

1. Tear open the sealed treatment kit and remove the Patch.
2. Place the Patch on a flat surface with the absorbent pads facing up.
3. Clean the treatment site thoroughly with alcohol prep by rubbing for six to eight seconds to remove dry skin, oils and other contaminants. Allow the treatment site to dry completely.

⚠️ **CAUTION:** Failure to clean skin thoroughly may cause excessive skin irritation or burns.

**NOTE:** The Patch will not adhere sufficiently to skin with lotion, oil or dirt.

**NOTE:** Clip hair if necessary to improve skin contact. DO NOT shave.

4. Place approximately 1.5 ml of a water-soluble drug/solution on appropriate polarity pad (active pad). On the other pad (return pad), apply approximately 1.5 ml of supplied saline ampoule. Use negatively charged water-soluble drugs on the negative (-) drug pad and positively charged water-soluble drugs on the positive (+) drug pad to actively deliver the drug. For positive (+) polarity, use only drugs with Chloride (Cl-) counter ions.

**NOTE:** Fill volume is approximately 1.5 ml. Drug pads should be saturated but not overfilled. If the drug pads are overfilled beyond the saturation point, the pads may leak and directly affect the adhesion of the Patch to the treatment site.

**NOTE:** Supplied saline ampoules contain 3.0 ml. Use approximately half and discard the unused portion.

⚠️ **CAUTION:** Under-filling or failure to evenly distribute drug or saline onto active or return pads may cause excessive skin irritation or burns.

- DO NOT fill Patch while it is on the patient.
- DO NOT over or under fill drug pads.
- DO NOT use drugs that are not water-soluble.
- DO NOT use drug suspensions.
- DO NOT use a Patch that appears altered or damaged.
- DO NOT apply Patch to dirty, oily or lotioned skin.
- DO NOT use tap water or non-chloride drug solution on positive polarity because this may cause tattooing or staining.

5. Make sure that the treatment site has intact skin.

⚠️ **CAUTION:** Failure to follow these guidelines may result in skin irritation or burns.

⚠️ **WARNING:** DO NOT apply the Patch over damaged or denuded skin or other recent scar tissue, skin with ingrown hair, pimples or razor nicks, skin with wounds that have not healed or sunburned skin.
ADMINISTERING TREATMENTS

The I-Bresis™ System is designed to provide the following three treatment options:

I-Bresis™ Treatment
The Controller delivers current at 3 mA to the Patch for three minutes for a Skin Conductivity Enhancement (SCE), followed by the patient wearing the Patch for approximately one to two hours, resulting in a 40-80 mA-minute treatment respectively.

Standard Treatment
The Controller delivers current at 2, 3 or 4 mA to the Patch for 10-20 minutes, resulting in a 40 mA-minute treatment. For an 80 mA-minute treatment, repeat the treatment.

Patch-Only Treatment
The Patch delivers low level current over 2–4 hours, resulting in an approximate 40–80 mA-minute treatment respectively.

I-BRESIS™ MODE TREATMENT

NOTE: While using the Controller, should an in-process iontophoresis treatment need to be stopped or paused, DO NOT suddenly remove the Controller from the Patch without first switching off the Controller. To stop a treatment while the Controller is administering iontophoresis, press the ON/OFF button and wait a few moments for the Controller to turn off.

NOTE: For additional information on the Controller, refer to the Controller Instructions for Use.

1. Push the ON button on the Controller. The Green I-Bresis™ Light will blink slowly.
2. Attach the Controller to the Patch. The Patch connector (located at the center of the Patch) plugs into the slot on the back of the Controller. Ensure that the Patch connector is fully and securely engaged into the Controller—a click will be heard upon full engagement.
3. Position the patient so that there is no pressure on the Patch during treatment.
4. Press the START button to begin treatment. The green I-Bresis™ Light will blink more rapidly, then glow steadily.
5. After three minutes, the Controller will sound a beep and the lights will turn off automatically. This indicates that the Skin Conductivity Enhancement (SCE) is completed.
6. Remove the Controller from the Patch. The Patch will now continue to deliver the remainder of the iontophoresis treatment to the patient.
7. If the patient will be wearing the I-Bresis™ Patch outside of the clinic, review the “Instructions for Home Use” at the end of this document with the patient, and provide the patient with a copy of those instructions, if requested.

6. Remove the adhesive release liner from the hydrated Patch.
7. Apply the hydrated Patch so that the drug pad is over the treatment site and secure it by pressing the adhesive border. Avoid pressing directly over the pads. Pressing directly on the pads can cause leakage that will compromise adhesion to the patient.

NOTE: DO NOT tape or bind the Patch during treatment. Do not apply hot or cold therapy over Patch during treatment.
8. The average time to complete the dose is indicated in the following table. To prevent excessive dosing, the Patch automatically switches off iontophoresis after the maximum dose has been administered.

<table>
<thead>
<tr>
<th>I-Bresis™ Mode</th>
<th>40 mA-minutes</th>
<th>60 mA-minutes</th>
<th>80 mA-minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wear Time</td>
<td>1 hour</td>
<td>1.5 hours</td>
<td>2 hours</td>
</tr>
</tbody>
</table>

9. Instruct the patient to remove and discard the Patch after one to two hours for a 40 to 80 mA-minute dose respectively.

10. The Patch should be discarded in a receptacle out of the reach of children and pets. The Patch cannot be reused.

**STANDARD MODE TREATMENT**

**NOTE:** While using the Controller, should an in-process iontophoresis treatment need to be stopped or paused, DO NOT suddenly remove the Controller from the Patch without first switching off the Controller. To stop or pause a treatment while the Controller is administering iontophoresis, press the ON/OFF button and wait a few moments for the Controller to turn off.

**NOTE:** For additional information on the Controller, refer to the Controller Instructions for Use.

1. Press the ON/OFF button on the Controller. The Green I-Bresis™ Light will blink slowly.
2. Push the Standard Mode button on the Controller. The 2mA indicator light will blink slowly. Each additional depression of the button will scroll to the next setting—3mA or 4mA.
3. Attach the Controller to the Patch. The Patch connector (located at the center of the Patch) plugs into the slot on the back of the Controller. Ensure that the Patch connector is fully and securely engaged into the Controller—a click will be heard upon full engagement.
4. Position the patient so that there is no pressure on the Patch during treatment.
5. Press the START button to begin treatment. The Green mA Light will blink more rapidly, then glow steadily.
6. To change the iontophoresis current setting while the Controller is administering a treatment, press the Standard Mode button to re-select the desired setting. Within a few moments, the Controller will automatically adjust to the new setting.
7. In 10–20 minutes (see following table) the Controller will sound a beep and the lights will turn off, indicating the 40mA-minute treatment has been completed.

<table>
<thead>
<tr>
<th>Standard Mode</th>
<th>40 mA-min</th>
<th>80 mA-min</th>
</tr>
</thead>
<tbody>
<tr>
<td>2mA</td>
<td>20 minutes</td>
<td>Repeat steps 1–2 and 5–7</td>
</tr>
<tr>
<td>3mA</td>
<td>13 minutes</td>
<td>Repeat steps 1–2 and 5–7</td>
</tr>
<tr>
<td>4mA</td>
<td>10 minutes</td>
<td>Repeat steps 1–2 and 5–7</td>
</tr>
</tbody>
</table>

8. Remove the Controller from the Patch.
9. Remove and discard the Patch after the treatment has been completed. The Patch cannot be reused.
PATCH-ONLY TREATMENT

1. Review the “Instructions for Home Use” at the end of this document with the patient, and provide the patient with a copy of those instructions, if requested. If the patient will be applying additional Patches at home, provide the patient with a copy of this instruction booklet.

2. The average time to complete a Patch-only dose is indicated in the following table.

<table>
<thead>
<tr>
<th>Patch Wear Time</th>
<th>40 mA-minutes</th>
<th>60 mA-minutes</th>
<th>80 mA-minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 hours</td>
<td>3 hours</td>
<td>4 hours</td>
<td></td>
</tr>
</tbody>
</table>

3. Instruct the patient to remove the Patch after the times shown above for the appropriate dose indicated in the table.

4. The Patch should be discarded in a receptacle out of the reach of children and pets. The Patch cannot be reused.

PATCH MATERIALS AND PH BUFFER

<table>
<thead>
<tr>
<th>Component</th>
<th>Material</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conductive Element</td>
<td>Polyester film, silver ink, silver/silver chloride ink, dielectric ink,</td>
</tr>
<tr>
<td></td>
<td>carbon, fluid barrier.</td>
</tr>
<tr>
<td>Battery Case</td>
<td>Lexan Polycarbonate, translucent.</td>
</tr>
<tr>
<td>Batteries</td>
<td>Two 3-Volt Lithium Ion Coin Cells, CR927.</td>
</tr>
<tr>
<td>Battery hardware</td>
<td>Springs: nickel-coated music wire. Resistive strip: white Mylar with</td>
</tr>
<tr>
<td></td>
<td>carbon flood coat one side.</td>
</tr>
<tr>
<td>Insulator</td>
<td>White polyethylene foam with medical grade pressure sensitive clear</td>
</tr>
<tr>
<td></td>
<td>acrylic adhesive double-coated.</td>
</tr>
<tr>
<td>Loaded Matrix</td>
<td>Nonwoven white polyester matrix, Gel sol (viscosity-enhancing agent)</td>
</tr>
<tr>
<td></td>
<td>composed of Polyethylene Oxide, Tween-20, and BHT.</td>
</tr>
<tr>
<td>Fluid Barrier</td>
<td>Single coated medical pressure sensitive polypropylene film.</td>
</tr>
<tr>
<td>Release Liner</td>
<td>Douglas-Hanson liner #92 or #96, coating blend on release side.</td>
</tr>
</tbody>
</table>
EXPECTED LIFE AND DISPOSAL

- The Best If Used By date for the Patch is shown on the Patch package and carton. The Patches may not be effective if they are used past the Best If Used By date.
- The Patch is designed for only one use. It will not work a second time. After the treatment, discard the used Patch in a receptacle out of the reach of children and pets. Do not dispose of the Patch in fire or an incinerator.

INSTRUCTIONS FOR HOME USE

If you are wearing the Patch home after treatment you need to know the following information:

- You may feel a slight tingling, prickling, or warm sensation from the I-Bresis™ treatment, but it should not be painful. If the treatment becomes painful or if you feel burning or undue sensation, remove the Patch and contact your clinician or DJO LLC.

While wearing the Patch, observe the following Warnings and Precautions:

- The electrodes can be worn during normal activity. However, excessive motion where the electrodes have been placed can cause poor contact between the skin and the electrode or uneven distribution of current, resulting in greater risk of skin irritation.
- Do not bind or apply pressure to the Patch as this may result in uneven contact which can increase the chance of skin irritation or burns.
- Do not wear the Patch during Magnetic Resonance Imaging (MRI) scans as this may result in metal overheating and causing skin burns in the area of the Patch.
- Handle the Patch with care. Do not immerse the Patch in fluids or allow it to be connected with other electrical devices. Do not use the Patch at temperatures above 40°C (104°F) or expose it to intense heat. Do not drop, abuse, or in any way exceed normal use. Misuse may cause the device to malfunction in ways that may lead to shock or burns.
- Devices that intentionally emit radio-frequency radiation may interfere with the operation of the Patch. If you feel that the delivery from the Patch changes when you are in the vicinity of such equipment, move further away from the equipment.
Removing the Patch:
Remove the Patch after the time determined by your clinician. Do not wear the Patch longer than four hours. Wearing the Patch longer increases the risk of skin irritation.

After removing the Patch, rinse the treatment area and pat dry with a clean cloth.

The Patch is designed for only one use. It will not work a second time. After the treatment, some drug solution will remain on the Patch which could be harmful to children or pets. Discard the used Patch in a receptacle out of the reach of children and pets. Do not dispose of the Patch in fire or an incinerator.

The following skin reactions may occur after iontophoresis treatment:

- A transient erythematos reaction, characterized by a uniform red pattern, can sometimes occur directly under the electrodes. The redness usually disappears within a few hours after treatment. Avoid scratching this area. Contact your clinician if this problem persists longer than 24 hours.
- Small pinhead size blisters may develop in response to certain drugs. Do not scratch these blisters. Contact your clinician if the problem persists longer than 24 hours.
- On rare occasions, iontophoresis therapy can result in temporary skin reactions such as rash, inflammation and irritation. These skin reactions may be the result of your sensitivity to the ionic solution used, the condition of your skin at the onset of treatment, reaction to the materials in the electrodes, or a poor connection between the electrode and your skin. If a visible skin reaction does occur, consult your clinician or the prescribing physician.

Please contact your clinician if you need assistance setting up or using the I-Bresis™ Patch or to report any unexpected operation or events.

ORDERING

<table>
<thead>
<tr>
<th>Order Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1360</td>
<td>I-Bresis™ Charging Station</td>
</tr>
<tr>
<td>1361</td>
<td>I-Bresis™ Controller</td>
</tr>
<tr>
<td>5000060</td>
<td>I-Bresis™ Patch</td>
</tr>
</tbody>
</table>
**PATCH SPECIFICATIONS**

**Classifications:** Internally Powered. Type BF Applied Part

**Battery:** Contains two 3-Volt non-rechargeable lithium manganese dioxide button cell batteries

**Environmental Conditions:**
- **Storage:** 15°C - 30°C (59°F - 86°F)
- DO NOT expose to temperatures above 50°C (122°F)

**Flammability:** Do not use around flammable gasses, liquids or materials

**Treatment Modes:** I-Bresis™, Standard, and Patch Only

**Dimensions:** 13.7 cm L x 6.6 cm W x 1.1 cm H (5.4” x 2.6” x 0.4”)

**Weight:** 6 g (0.2 oz.)

**Disposal:** Dispose according to local, state and federal regulations.

**Dose range:** 0-80 mA-minutes

**Maximum Voltage:** 6.8 V (Patch only)

**Maximum Current:** 3.4 mA (Patch only)

**Number of uses:** The Patch is designed for only one use.