Instructions for Use Polyamide Match Point System™ guides and models

This document contains general instructions for use for polyamide Match Point System™ guides and models. For case-specific instructions please refer to the Case Report.

DEVICE DESCRIPTION
Match Point System™ guides and models are patient specific devices designed to fit or represent the patient's anatomy. They are intended for surgical interventions in orthopaedic procedures for total and reverse shoulder arthroplasty.

COMMON NAME: patient specific instrumentation for shoulder arthroplasty

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE
The Match Point System™ is intended to be used as a surgical instrument to assist in the intraoperative positioning of glenoid components used with total and reverse shoulder arthroplasty procedures which utilize anatomic landmarks that are identifiable on preoperative CT or MRI medical images.

The Match Point System™ can be used with the following total and reverse shoulder implant systems and their respective compatible components: Encore Shoulder System (K051075), Turon™ to RSP Conversion Shell (K111629), Turon™ Shoulder System (K080402) and Reverse® Shoulder prosthesis (K092873).

The Match Point System™ guides are intended for single use only.

MATERIAL: Polyamide

CONTRAINDICATIONS
Patients with conditions or diseases such as scapular fractures, metabolic bone diseases (such as Paget’s Disease), heterotrophic ossifications or ligament calcifications, skeletal dysplasia, neoplasms or other disorders that affect scapular anatomy and bony landmark recognition.

Patients exhibiting conditions which are out of the borders tested for safety and effectiveness for Match Point System™ guides:

- Version greater than 40° or less than -40°
- Inclination greater than 45° or less than -10°

Active infection of the surgical area where the surgery will be performed is a contraindication for Match Point System™ guides.

WARNINGS
- If the device is unable to be used for any reason, the surgeon should be prepared to use conventional instrumentation to perform the procedure.
- The user should be aware of possible allergic reactions to materials used in the guide or model. The patient should be informed on this matter by the user.
- The user should consult the instructions for use and surgical technique of respective implant system and their compatible components for the indications, warnings, precautions, adverse effects and contraindications.
- These are patient-specific, single use, disposable guides and models.
- Do not attempt to reuse or recondition the guides or models.
- Do not alter the guides or models from their original shape. Debris from the alteration could contaminate the operating region. In addition, altering the size of the guide may lead to an improper fit on the patient’s anatomy.
- Do not use the guide if full surface contact is not achieved between the guide and the underlying patient’s anatomy. Pressure must be placed on the guide according to the push direction maintain contact during use. Loss of contact between the guide and the underlying anatomy may result in improper pin position.
- Match Point System™ guides are to be used by a trained physician in the performance of surgery.
• Be aware that these patient-specific guides and models have been manufactured based on CT/MRI scans of the patient. If the patient’s anatomy has changed significantly since the time of the CT/MRI scan, the guides or models should not be used.

• The guides and models should be properly cleaned before sterilization. Do not use if the guides are broken, cracked, or are visibly contaminated or if the stainless steel tubes (if present) are not tightly secured.

• The guides and models in this package are provided non-sterile. The guides and models in this package must be sterilized prior to use.

PRECAUTIONS
• It is advised to use the guide or model within 6 months after performing the CT/MRI scans on which they are based. If the patient’s anatomy has changed significantly since the time of the CT/MRI-scan, the guide or model should not be used, even if the time period of 6 months is not expired.

• Do not apply excessive force on the guides or place heavy objects on top.

• Markings on guides used for indicating anatomical references and case information must be legible. These include lines indicating anatomical directions, identifiers with case information such as case identifier (see below). Notify your Materialise representative if the markings are not legible or if the identifiers do not correspond to the intended patient or surgeon.

PATIENT SPECIFIC GUIDE IDENTIFIERS
An identifier is indicated on each guide and model. This alphanumeric code links the guide unambiguously to the patient case. Each patient case is accompanied with a Content of the Box form and a Case Report, which specify all delivered surgical instruments, together with their identifier and a graphical illustration.

Before using the guide, check the identifier for readability and confirm that it corresponds with the patient’s identity.

POSSIBLE ADVERSE EFFECTS
Infection following the surgical procedure. Introduction of foreign materials can result in an inflammatory response or allergic reaction.

INSTRUCTIONS FOR USE
For case specific instructions consult the case planning report for the approved position and any additional comments regarding the use of the guide before use intraoperatively.

Fitting of the guide

- The guide is designed to fit the patient anatomy. The fitting surface on the glenoid face and corticoid neck should be cleared of loose soft tissue to assure good fit of the guide. This surface is indicated in the planning report delivered with the device.

- Do not remove osteophytes or alter the glenoid bony anatomy before fitting the guide.

- Do not damage the bony surface where the guide makes contact with the patient.

- Compare the fit position of the guide to the planned fit position. The case report shipped with every guide indicates the position of the guide relative to the surrounding anatomy. The fitting position on the bone model should match the fitting position on the patient's anatomy.

- If it is not possible to place the guide on the patient in a stable position, the guide does not guarantee an accurate transfer of the pre-operative planning.

- Even in a stable position, it is possible that the guide does not make full contact with the bone over its entire surface, since it is not always possible to solve all of the undercuts. The undercuts depend on the shape of the patient’s anatomy. During the design of the guide the amount of undercut is kept to a minimum to ensure a maximal contact between the fitting surface and guide.

Guided drilling

- Verify that the correct drill diameter is being used which corresponds to the guide’s drill diameter.

- Do not intend to modify the drill direction by drilling through the drill cylinder’s surface.

- Verify full surface contact is achieved between the guide and the underlying patient anatomy with the exception of the 2mm offset over the superior glenoid ridge.

- Maintain pressure on the guide to keep contact between the guide surface and underlying patient anatomy during drilling.
CLEANING AND STERILIZATION INSTRUCTIONS

**Match Point System™** guides and models are **NOT STERILE** and must be thoroughly cleaned and sterilized prior to use

**Cleaning**

Rinse the guides and models under cold running tap water to remove gross soil. Use a soft bristled brush to remove soil from the surface of the guides and models. Use a syringe to flush cylinders and slots.

Immerse the guides and models in a detergent and allow them to soak for a minimum of 25 minutes. The detergent should be of neutral or near neutral pH (pH 7-11 like ELMA TEC CLEAN N1 detergent).

Use a soft bristled brush to remove soil from the surface of the guides and models. Use a syringe to flush cylinders and slots.

Remove the guides and models from the detergent and rinse them in running RO/DI water.

Dry the guides and models using a clean, soft lint-free cloth and filtered pressurized air.

**Sterilization**

**Recommended sterilization specifications**

The guides can be sterilized twice prior to use. The guides are intended for single use only. Users should conduct testing in the health care facility to ensure that conditions essential to sterilization can be achieved.

Sterilize the guides or models using **pre-vacuum steam sterilization** before use. During sterilization of single devices, pouches may be used. Only legally marketed, FDA cleared and validated sterilization pouches should be used by the end-user for packaging the devices during sterilization.

Use one of the following standard steam sterilization settings:

The cycles to use within USA:

- **Pre-vacuum Cycle** $^{1,2}$:
  - Minimum temperature: 270°F (132°C)
  - Minimum exposure time: 4 minutes
  - Minimum vacuum drying time: 30 minutes

The cycles to use outside USA:

- **World Health Organization Prevacuum Cycle** $^{2,3}$:
  - Minimum temperature: 273.2°F (134°C)
  - Minimum exposure time: 18 minutes
  - Minimum vacuum drying time: 30 minutes

**CONTACT DETAILS**

For any questions or concerns, please contact your Materialise representative and/or the Materialise customer service.

Comments or changes regarding the use of this device can be directed to attention of the manufacturer: Materialise USA LLC., Helm Court 44650, Plymouth MI, Fax: 734-662-7891.

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1 Minimum validated steam sterilization temperature required to achieve a $10^{-6}$ sterility assurance level (SAL).
2 In the case local or national specifications for steam sterilization requirements are stricter or more conservative than those listed in this table, please contact Materialise before sterilizing and using the guides.
3 Disinfection/steam sterilization parameters recommended by the World Health Organization (WHO) for reprocessing instruments where there is concern regarding TSE/CJD contamination.