Instructions for Use
Button Plate

This instruction for use is not intended for distribution in the USA.

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DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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Instructions for Use

Button Plate
Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding surgical techniques DSEM/TRM/0815/0447 carefully before use. Ensure that you are familiar with the appropriate surgical technique.

Material(s)

Material:	Standard:
TiCp	ISO 5832-2

Intended use
Button plates are intended for the reinforcement for transosseous fixations.

Indications
Rotator cuff tears (especially in osteoporotic bone).

Contraindications
No specific contraindications.

Potential Risk
As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common include:
Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, excessive bleeding, iatrogenic neural and vascular injury, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, Sudeck's disease, allergy/hypersensitivity reactions, and side effects associated with hardware prominence, malunion, non-union.

Sterile device

STERILE R Sterilized using irradiation

Store implants in their original protective packaging and do not remove them from the packaging until immediately before use.
Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use if the package is damaged.

Do not resterilize

Implantable devices labeled with "Do not re-sterilize" symbol must not be re-sterilized because re-sterilization may compromise the structural integrity of the device and/or in multipart devices re-sterilization cannot be guaranteed due to initial sterilization in a sterile assembly site.

Single-use device

Do not re-use

Products intended for single-use must not be re-used.
Re-use or reprocessing (e.g. cleaning and resterilization) may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury, illness or death.
Furthermore, reuse or reprocessing of single-use devices may create a risk of contamination, e.g. due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.

Contaminated implants must not be reprocessed. Any Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol. Even though they may appear undamaged, the implants may have small defects and internal stress patterns that may cause material fatigue.

Precautions
For general precautions consult the Synthes brochure "Important Information".
For application specific precautions related to Button Plate Implants, it is mandatory to consult the corresponding surgical technique (www.depuysynthes.com/ifu) of the product system being used.

Warnings
For general warnings consult "Important Information".
For application specific warnings related to Button Plate Implants, it is mandatory to consult the corresponding surgical technique (www.depuysynthes.com/ifu) of the product system being used.

Combination of medical devices
Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

Magnetic Resonance environment
When a device has been evaluated for use in the MR environment, MRI information will be found in the surgical technique at www.depuysynthes.com/ifu

Treatment before device is used
Synthes products supplied in a non-sterile condition must be cleaned and steam-sterilized prior to surgical use. Prior to cleaning, remove all original packaging. Prior to steam-sterilization, place the product in an approved wrap or container. Follow the cleaning and sterilization instruction given by the Synthes "Important Information".

Processing/reprocessing of the device
Detailed instructions for processing of implants and reprocessing of reusable devices, instrument trays and cases are described in the Synthes brochure "Important Information". Assembly and disassembly instructions of instruments "Dismantling multipart instruments" can be downloaded from
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

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