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01-50-1286
Revision C
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Move Forward Software Version 1.1

ATTENTION OPERATING SURGEON

DESCRIPTION
The Move Forward 3D Motion Simulation Service is an online image analysis service that enables clinicians to obtain 3D motion simulation reports based on CT or MR image data. This service consists of three modules: CGOnline, Arbiter, and Articulis.

During the segmentation process, 3D bone models of the pelvis and femur bones are created from the image data. Any required editing of the segmentation images are performed by Zimmer Biomet operators. These 3D bone models are then used to perform 3D motion simulations of the hip joint. The 3D motion simulations can be used to visualize rigid shapes such as bones that come into contact with one another, thus potentially limiting range of motion. The system includes several calculated intersection zones that each individually improve the simulated range of motion. The system also calculates several morphological shape parameters for each of the 3D bone models.

The software generates an interactive PDF report as output, which Zimmer Biomet delivers to clinicians on a per case basis through the CGOnline module. In particular, the report that is generated provides information to the clinicians associated with femoroacetabular impingement (FAI). Clinicians do not interact with the image analysis software directly. The Articulis and Arbiter modules are only operated by Zimmer Biomet operators who have been specifically trained for this purpose. End users of the generated Move Forward reports are trained medical professionals, including radiologists and orthopedic surgeons.

INDICATIONS FOR USE
Zimmer Biomet's Move Forward 3D Motion Simulation Service is an online image analysis service for skeletally mature individuals that enables clinicians to obtain 3D motion simulation reports based on CT or MR image data.

The service can be used by uploading either CT or MR image data of hip joints. The image data is processed by Zimmer Biomet to create 3D anatomy models. These 3D models are then used to perform 3D motion simulations of the hip joint. The report also provides several calculated intersection zones that may improve the simulated range of motion. Move Forward also calculates several morphological shape parameters for each of the 3D anatomy models.

The software generates an interactive report as an output. Clinicians do not interact with the image analysis software directly. The image analysis software is only operated by Zimmer Biomet operators who have been specifically trained for this purpose. End users of the generated Move Forward reports are trained medical professionals, including radiologists and orthopedic surgeons.

WARNINGS

1. The Move Forward 3D Motion simulation reports are intended for clinical experts only. The reports are computed using analysis software and represent a simplified model of clinical reality. The Move Forward 3D Motion simulation reports are not intended as a replacement for established methods used for the diagnosis and evaluation of pathologies and/or injury. Medical and health care providers should exercise their own independent clinical judgement.
2. The motion simulations of the Move Forward 3D Motion simulation service only take into account rigid shapes such as bones. Soft tissues are excluded from the simulations. Therefore, simulations results are to be considered a conservative estimate, possibly underestimating the extent of motion limitations.
3. Immediately stop using the Move Forward 3D Motion simulation reports if the 3D viewer does not function well or does not activate.
4. The visualization of the intersection zones and their 3D motion simulations should not be interpreted as an instruction to remove specific areas of bone in a surgical procedure.

CONTRAINDICATIONS
The Move Forward 3D Motion Simulation Service is contraindicated as follows: 1. Previous hip surgeries that include the placement of metal components 2. Patients with severe arthritis 3. Patients with hip dysplasia 4. Deformities of the proximal femur and femoral head 5. When the hip may not be constrained to rotational movements.

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

Comments regarding the use of this device can be directed to Attn: Regulatory Affairs, Biomet, Inc., P.O. Box 587, Warsaw, IN 46581 USA, Fax: 574-372-3968.

CE Mark on the package insert (IFU) is not valid unless there is a CE Mark on the product (description) label.

EC REP Authorized Representative: Biomet U.K., Ltd.
Waterton Industrial Estate
Bridgend
CF31 3XA
United Kingdom

CE

Symbol Legend
Manufacturer
Date of manufacture

 Do not reuse

Do not resterilize

 Caution, see instructions for use

STERILE EO Sterilized using ethylene oxide

STERILE R Sterilized using irradiation

STERILE Sterile

STERILE A Sterilized using aseptic processing techniques

STERILE Sterilized using steam or dry heat

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

 Do not use if package is damaged (Pack Damaged)

 Use by date

 WEEE device

REF Catalogue number

LOT Batch code

Flammable

EC REP Authorized representative in the European Community