Health Technology Review	
Technology Ref.:	HTA22018
Technology Name:	Mako Robotic Assisted Hip and Knee Replacement
Approvals by International Bodies:	FDA, MHRA ref 12441
Company name:	Stryker. COO: United States
Agent in UAE:	Healthpoint
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Short Description of the Technology:	**Mako Robotic** Assisted Hip and Knee Replacement is widely available across the world including the UK, USA, Europe and Australia. The system has been available in the USA for 10 years. The system includes pre-operation planning using a CT scan to optimize implant size and positioning prior to surgery. During surgery a Robotic arm is used to accurately place the hip or knee replacement. There is evidence that with accurate placement of implants joint replacements have less wear and last longer. Complications such as dislocation and leg length discrepancy are reduced. Differences include the requirement for bone pins for computer tracker placement during the procedure and 2 small reference pins all removed at the end of the procedure. All patients require a CT scan prior to the operation.

Health Technology Assessment Team Recommendation:	**Approve**

Summary of Review:

Mako Robotic Assisted Hip and Knee Replacement is widely available across the world. The system has been available in the USA for 10 years.The surgeon uses the system to create a pre-operative plan, mapping out the ideal position and orientation of the implant. Below are some advantages and disadvantages based on international reviews and received studies and researches.

Advantages	Disadvantages
Safety is improved. With the MAKO system turned on, surgeons can only perform within their pre-operative plans due to the robot restricting cutting outside of the pre-planned area. This reduces the risk of human error	Small risks from a CT scan and tracker pin placement
The technology will improve accuracy and outcomes and give the local community access	Surgical time is likely to be slightly longer than with traditional joint replacements, exposing

to high healthcare technology	patients to theoretically greater risk of infection
There is evidence that with accurate placement of implants joint replacements have less wear and last longer	The cost of the procedure is also slightly more than a conventional joint replacement because a CT scan is required of the joint to plan the procedure, although at 90-day episode of care, researchers found a $2,391 cost savings with Mako
Reduced the risk of complications such as dislocation and leg length discrepancy	Any computerized system is only as good as the information that is inputted into it. This includes the quality of the initial CT scans, and the proficiency of the team using the MAKO system. Appropriate training and experience helps the workflow process and optimally the final surgical result achieved.
Improved recovery, complications and longevity	This is a new technology for joint replacement implantation and, as such, there is only early evidence to show long-term enhanced implant performance. The actual implants used are already traditionally tried and tested prostheses.
The financial impact is that the utilization of introducing the robotics technology which includes the preparation/programming the robot.	Data transferred outside the country required to comply with DOH InfoSec guidelines
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Robotic-arm assisted total knee arthroplasty is associated with improved early functional recovery and reduced time to hospital discharge compared with conventional jig-based total knee arthroplasty	
The risk of blood loss is reduced and there is an improvement in safety levels, as the system only allows them to perform the procedure within the area mapped out by their pre-op plan	

We recommend an **approve of using this technology** with the following conditions:

1. The surgeon must be trained and certified on operating the robot beforehand.
2. The use of technology in hospitals and centers that are well-equipped with all needed medical equipment's and devices.
3. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees and patients.
4. Provision of regular updates and reports outcome about the product to DOH upon request.

Moreover, DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

Technology Image


Population, setting and intended user for Technology "Mako Robotic Assisted Hip and Knee Replacement"

- **Population/ Intended User**;
  - Patients for knee and hip replacement
- **To be performed by**:
  - By Certified Surgeons
- **Clinical Setting:**
  - Hospitals, special surgery centers
- **Condition of use:**
  - The surgeon must be trained and certified on operating the robot beforehand
- **Exclusion criteria:**
  - Patients with active infection
  - Patients without sufficient bone stock to allow appropriate insertion and fixation of the prosthesis
  - Patients without sufficient soft tissue integrity to provide adequate stability
  - Patients with either mental or neuromuscular disorders that do not allow control of the knee joint;
  - Patients whose weight, age or activity level might cause extreme loads and early failure of the system