



Circular No. 12 / 2022

21 -06-1443 H

24 -01-2022

بنقدم بثقة  
Moving Forward  
with Confidence



**Field Safety Corrective Action of Micra leadless pacemaker from Medtronic SA.**

Source	GHC-Gulf Health Council.
Product	Micra leadless pacemaker.
Manufacturer	Medtronic SA.
Local Agent	Al Zahrawi Medical Supplies LLC.
The affected products	All.
Reason	There is Risk of major complications if cardiac perforation occurs during leadless pacemaker implantation
Action	<ol style="list-style-type: none"><li>1. Discuss the risks and benefits of available pacemaker system options with patients as part of shared clinical decision-making.</li><li>2. Read and carefully follow the Instructions for Use (IFU) and training for the Medtronic leadless Micra Transcatheter Pacing System, which include recommendations about implant location at the right ventricle septum, delivery system steering, repositioning the device, patient selection to minimize perforation risk, stand-by availability of cardiothoracic surgery, and immediate access to echocardiography equipment.</li><li>3. Contact the local agent for remedial action.</li></ol>
Product Picture	
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control contact E-mail: <a href="mailto:Med-device@moh.gov.om">Med-device@moh.gov.om</a>

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL





To:

**THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES**  
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)  
Director General of Engineering Affairs; MOH  
Director General of Royal Hospital  
Director General of Khoula Hospital  
Director General of Medical Supplies (MOH)  
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)  
Hospital Director (Al Nahda Hospital)  
Hospital Director (Al Massara Hospital)  
The Head of Medical Services in SQU Hospital  
The Head of Medical Services in Royal Oman Police  
The Head of Medical Services in Ministry of Defence  
The Head of Medical Services in The Diwan  
The Head of Medical Services in The Sultan's Special Force  
The Head of Medical Services in Internal Security Services  
The Head of Medical Services in Petroleum Development of Oman  
The Head of Medical Services in LNG Oman  
**ALL PRIVATE PHARMACIES & DRUG STORES**

After Compliments,

Please find attached our Circular No. 12/2022 dated 24/1/2022 Regarding GHC FSCA of Micra leadless pacemaker from ( mrf: Medtronic SA).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information



## تقارير السلامة للأجهزة والمستلزمات الطبية Safety Alerts of Medical Device Products

<b>To:</b> HE / Members of the Executive Committee of the Cooperation Council States Members		<b>إلى:</b> سعادة/ أعضاء الهيئة التنفيذية بدول مجلس التعاون.	
<b>Subject:</b>	تحذير سلامة للمنتج الطبي (Micra leadless pacemaker) من أنتاج شركة (Medtronic SA)		<b>الموضوع:</b>
<b>Product Name:</b>	Micra leadless pacemaker		<b>اسم المنتج:</b>
<b>Company:</b>	Medtronic SA		<b>الشركة:</b>
<b>Affected product:</b>	ALL		<b>المنتجات المتأثرة:</b>
<b>Reg. Status in GHC:</b>	Not registered		<b>وضع المنتج في مجلس الصحة:</b>
<b>Source of Warning:</b>	SFDA		<b>مصدر التحذير:</b>
<b>Reason for Warning:</b>	SFDA status that there is Risk of major complications if cardiac perforation occurs during leadless pacemaker implantation.		<b>سبب التحذير:</b>
<b>Recommendation:</b>	SFDA recommended that: <ul style="list-style-type: none"><li>Discuss the risks and benefits of available pacemaker system options with patients as part of shared clinical decision-making.</li><li>Read and carefully follow the Instructions for Use (IFU) and training for the Medtronic leadless Micra Transcatheter Pacing System, which include recommendations about implant location at the right ventricle septum, delivery system steering, repositioning the device, patient selection to minimize perforation risk, stand-by availability of cardiothoracic surgery, and immediate access to echocardiography equipment.</li><li>Report any adverse events or suspected adverse events experienced with the Micra Transcatheter Pacing System or other pacemaker systems.</li></ul>		<b>التوصيات:</b>
<b>Authorized Representative</b>	<b>AR name:</b>	Medtronic Saudi Arabia	<b>الشخص الممثل:</b>
	<b>Assigned Contact Person:</b>	Alsurrayi, Nahar	
	<b>Mobile/Phone:</b>	+966) 555066900	
	<b>Email:</b>	<a href="mailto:nahar.s.alsurrayi@medtronic.com">nahar.s.alsurrayi@medtronic.com</a>	
<b>Link of Circular</b>	For more information, please click <a href="#">here</a>		<b>رابط التعميم:</b>
<b>For inquiries and reporting:</b>	<a href="mailto:pms@ghc.sa">pms@ghc.sa</a>		<b>للاستفسارات والإبلاغ:</b>