

Medtronic



SynchroMed™ II Drug Infusion System

# Targeted Drug Delivery for patients with refractory cancer pain.

Cancer pain is a significant problem,  
and it's growing.<sup>1</sup>

# Quality of life impact

Cancer patients perceptions of their pain:

67%

describe it as distressing<sup>3</sup>

About

25%

of cancer patients die in pain<sup>2</sup>

32%

describe their pain as so bad they wish they would die<sup>3</sup>

Cancer pain has a detrimental impact on patients & their families.

Cancer pain contributes to impaired performance of daily activities, disability, negatively affects mental health, and reduces health related quality of life.<sup>3</sup>



# Barriers to seeking cancer pain analgesia

Barriers to seeking adequate cancer pain relief include:

- **Reluctance to report pain**, due to the belief that healthcare professionals must be focused on the cancer itself<sup>4</sup>
- **Belief that pain is an inherent part of cancer** and fears that higher pain levels, increased analgesia needs, and the symbolic significance of opioids indicate disease progression, deterioration and approaching death<sup>5</sup>
- **Fear of side effects** and addiction associated with perceptions of opioids use<sup>4</sup>

Educational resource  
for your patients.



The Breivik<sup>3</sup> publication (2009) stated that 50% (289 of 573) of the **patients believe that their HCP does not consider their QoL as an important aspect of the overall care plan.**



// I don't want to let them see I'm in pain, so I have to hide it."

Patient-reported extract from a study of narrative interviews with severe chronic cancer pain patients, from a single centre in Italy<sup>6</sup>



# The benefits of targeted drug delivery for cancer pain patients

- The efficacy of TDD for the treatment of cancer-related pain has been demonstrated in randomized controlled clinical trials.<sup>9,10</sup>
- **A lower morphine equivalent dose is needed** via intrathecal application.<sup>8</sup>
- Targeted drug delivery (TDD) via the intrathecal route **offers significant benefits to cancer pain patients who are not optimally managed** on oral or transdermal analgesia. The smaller doses may reduce the systemic side effects.<sup>9,10,15</sup>

## Intrathecal

Targeted drug delivery (TDD) directly to the cerebral fluid

## Oral

Systemic delivery through the circulatory system

This mode of drug administration allows delivery of smaller doses (up to 300x lower)

Route of Administration	Conversion Ratio
Oral	300
Intravenous	100
Epidural	10
Intrathecal	1

Morphine equivalent dose across different routes of morphine administration<sup>8</sup>

# The procedure: clinical considerations

Patient selection, trial, implant and refill management.

## TDD procedure

Oncological treatments/follow up



### Patient selection



### Trial

- Simple lumbar puncture
- Medications delivered via needle or catheter
- Evaluate therapy efficacy



### Implant

- Time: 1-2 hours
- May be performed under general/local anesthesia
- Two incisions: Catheter and Pump
- Relative size of the pump



### Titration and Refill

- Dose optimization
- 22 gauge needle
- No sedation required

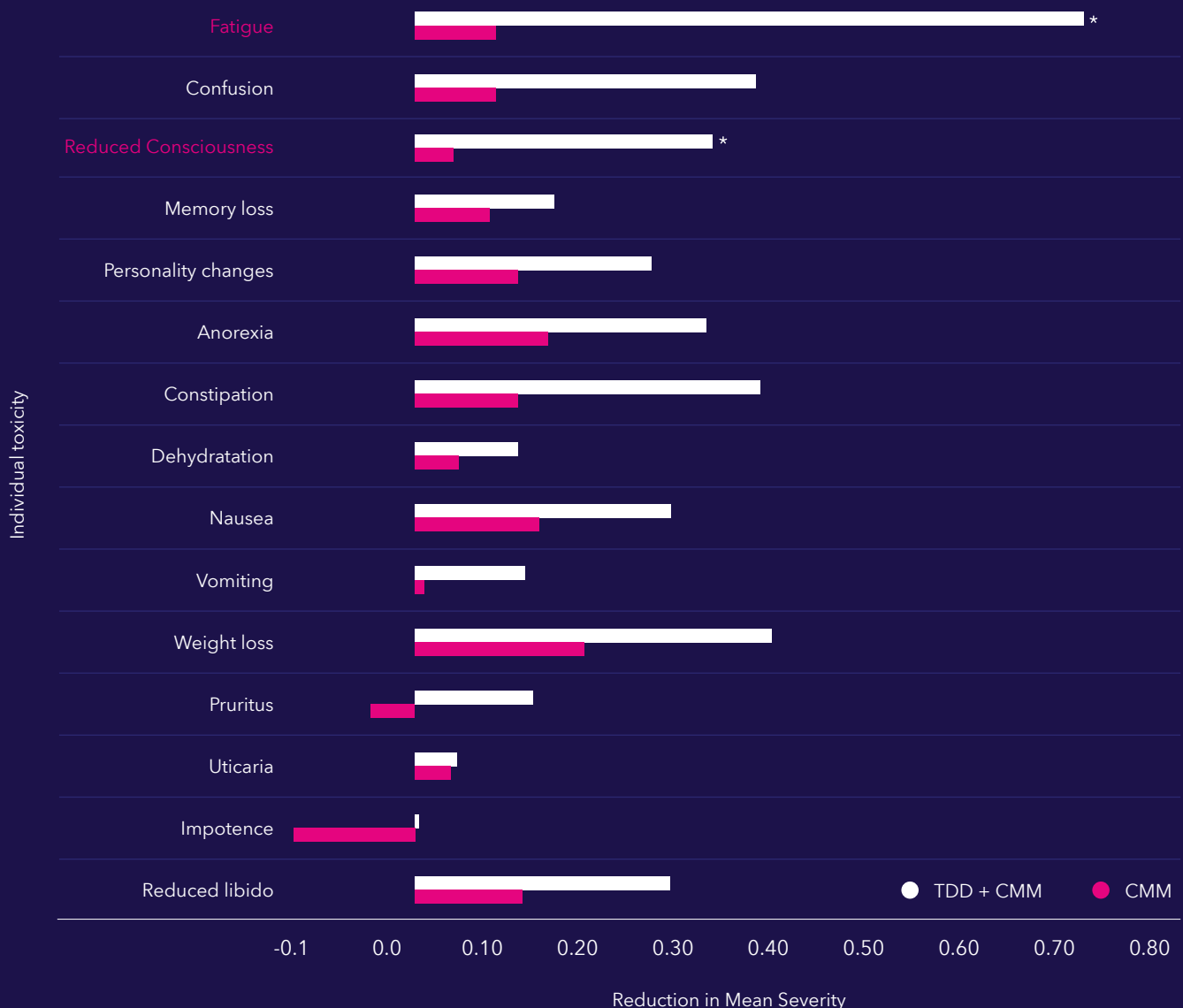


# Clinical evidence supports TDD delivery for chronic cancer pain

International, multicenter study assessing TDD + conventional medical management

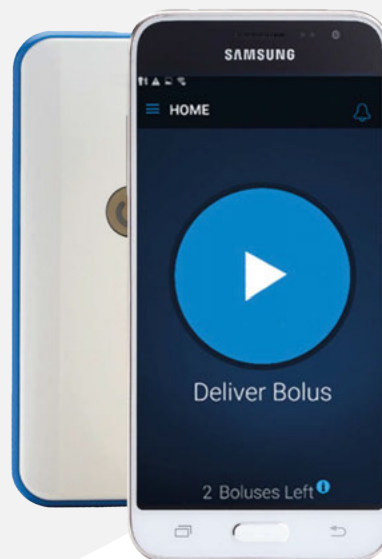
Reduction in individual toxicities from baseline to 4-week follow-up

More patients with less fatigue and reduced consciousness.<sup>9</sup>



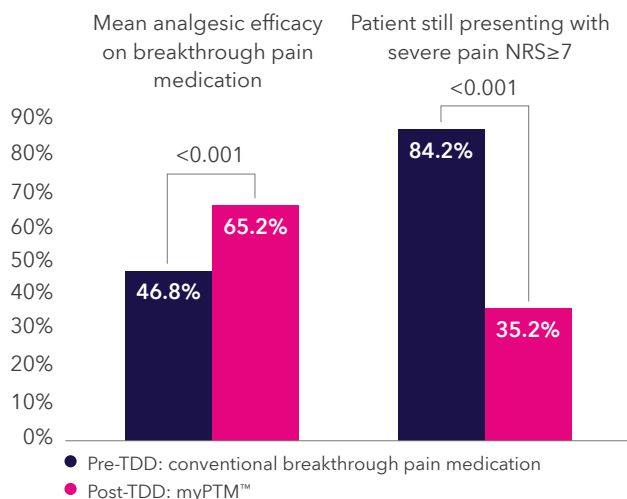
# Benefits for breakthrough cancer pain

BTCP has a major impact on patients' quality of life, thus research into new treatments and alternative treatment administration routes should be investigated.<sup>16</sup>

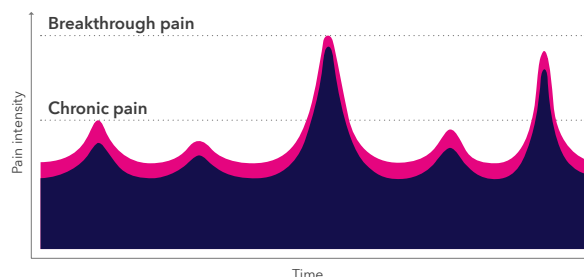


## With myPTM™

- achieve better control of breakthrough pain
- 3x faster compared to conventional medication.<sup>14</sup>



- Breakthrough pain reduction was **46.8% before implant and 65.2% after implant** and with myPTM™<sup>14</sup>
- Patients with severe pain were **84.2% before implant and 35.2% after implant** and myPTM™<sup>14</sup>
- With myPTM™ patients can manage breakthrough pain **quicker compared to systemic opioids** (10 vs 30 min on average)<sup>14</sup>



Targeted drug delivery (TDD) with myPTM™ allows for patient control of breakthrough pain – within programmed parameters – ensuring 100% compliance. When pain is breakthrough, your prescription is right at hand.

## Managing pain & breakthrough pain 3x faster, with less side effects!

# Considerations for appropriate patients

Patient selection recommendations



Medium to long-term life expectancy  
(typically  $\geq 3$  months)<sup>9,15</sup>



Visual analogue score (VAS)  $\geq 5$  despite 200 mg/day  
of oral morphine or analgesic equivalent<sup>9,10</sup>



Side effects not well tolerated  
on lower dose analgesics<sup>9,10,12</sup>



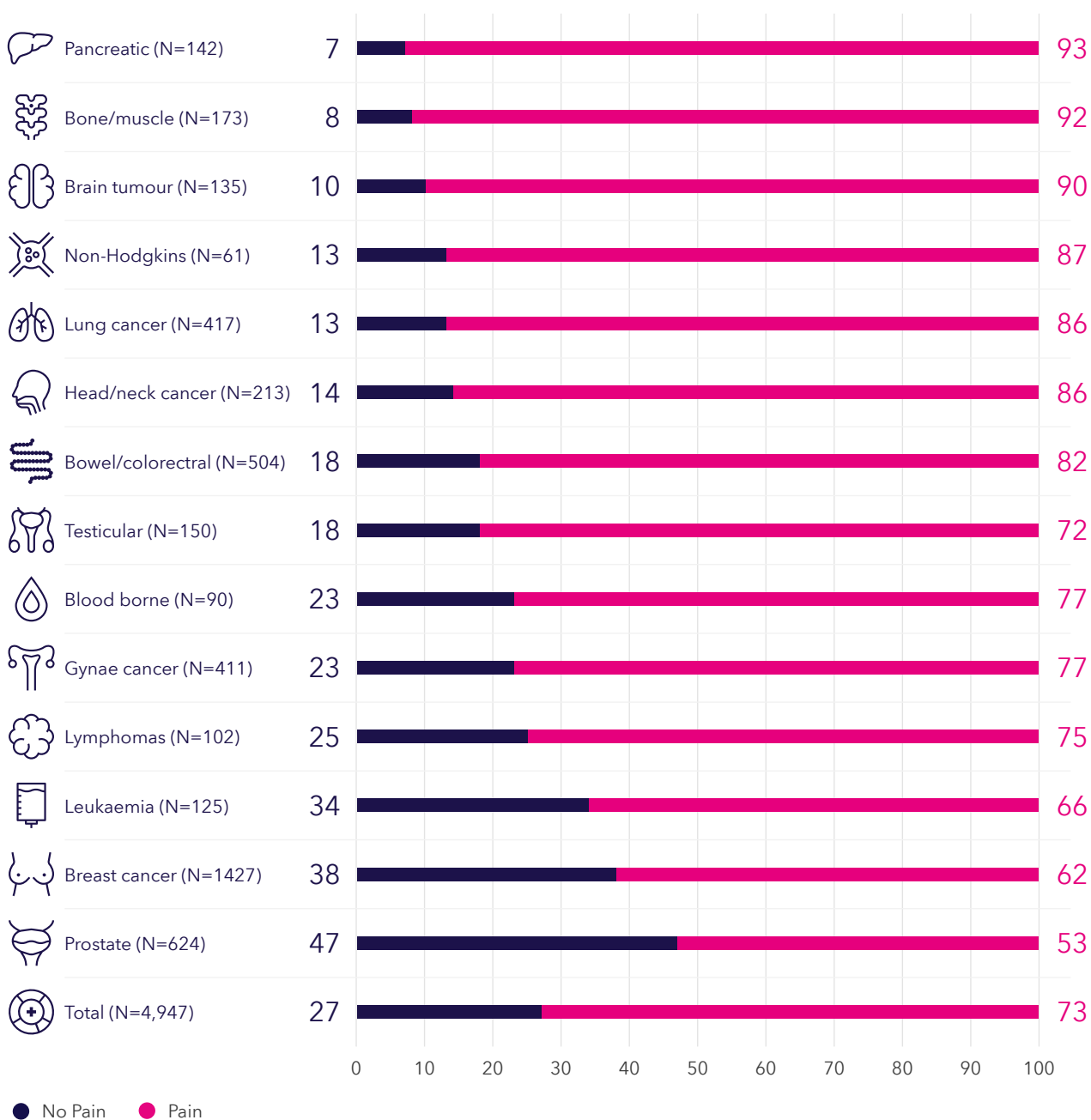
In your assessment, talk to the patient about  
their goals and expectations





14% of patients are suffering from refractory pain according to Meuser et al.<sup>19</sup>

### Prevalence of pain by cancer type (% of patients)<sup>3</sup>



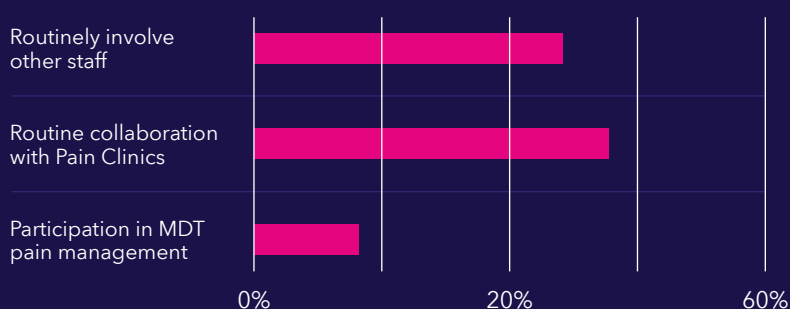
# Recommendations

## Intrathecal drug delivery for cancer-related pain

Guideline and society (year)	Recommendations for intrathecal drug delivery
European Pain Federation (EFIC) (2018) <sup>11</sup>	<p><b>Patients should be referred to specialist advice and treatment</b> if pain is not improving within a short time or if they are experiencing intolerable side effects of analgesia [GRADE 1C]</p> <p>This includes access to advanced pain management techniques such as intrathecal pumps.</p>
European Society for Medical Oncology (ESMO) (2018) <sup>17</sup>	<p>Level II B - Intraspinal techniques delivered and monitored by a skilled team <b>should be included as part of the cancer pain management strategy</b></p>
Polyanalgesic Consensus Conference (PACC) convened by the International Neuromodulation Society (2017) <sup>12</sup>	<p>Localized pain can be adequately covered with intrathecal therapy (II B Strong)</p> <p>Diffuse pain can be adequately treated with intrathecal therapy (III C Moderate)</p> <p>Global pain can be adequately treated with intrathecal therapy (III D Moderate)</p>
European Association for Palliative Care (EAPC) (2012) <sup>13</sup>	<p>Spinal (epidural or intrathecal) administration of opioid analgesics in combination with local anaesthetics or clonidine should be considered for patients in whom analgesia is inadequate or who have intolerable adverse effects despite the optimal use of oral and parenteral opioids and non-opioid agents. (Weak Recommendation)</p>

## Inequalities of access to optimized cancer pain treatments

### Survey of oncologist involvement in cancer pain management\*



**Multidisciplinary management and collaboration between oncologists and other specialists remains uncommon.<sup>7</sup>**

# Clinical evidence supports TDD for chronic cancer pain

## Systematic Review & Meta-Analysis:

Management of intrathecal drug delivery (Perruchoud et al. 2021)<sup>18</sup>



### Objectives

To examine the efficacy of managing cancer-related pain with IDD with external pump or implanted infusion systems. Secondary objectives included the effects of IDD on systemic opioid use (oral morphine equivalent [OME]) and infection rates.



### Results

Twenty-nine studies, 17 for calculating pain levels and 13 for weighted mean morphine dose, were identified.

Pain levels significantly decreased postintervention from baseline. Mean differences (on a 0 to 10 scale) were:

- 4.34 ( $p < 0.001$ ) at 4 to 5 weeks (short-term)
- 4.34 ( $p < 0.001$ ) at 6 to 12 weeks (mid-term)
- 3.32 ( $p < 0.001$ ) at >6 months (long-term)

Mean systemic opioid use (OME) was reduced by 308.24 (SE = 22.72) mg/d. (54% reduction of OME).

Mean infection rates were ~3% for intrathecal pumps, which is similar to that found in other populations treated with IDD implanted systems.

Survival - The pooled weighted mean survival time was 130.68 (SE = 1.50) days. This may have been possible due to reduced toxicity and a general improvement in the patients' QoL post-IDD.



### Study Design

A systematic literature search according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.



### Limitations

Meta-analysis could not be performed based on control group values because of the heterogeneous designs of the selected studies.

A substantial intertrial heterogeneity was found, as anticipated from the variability in study designs.

Complications, adverse events, and drug side effects were not consistently collected and/or analyzed across selected studies.



### Key Insights

This 2021 published meta-analysis showed a statistically significant and sustained decrease in cancer pain with IDD, compared with baseline.

Systemic opioid consumption was reduced on average by >50% after IDD. Infection rates were comparable with other indications.

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## Brief statement:

See the device manual for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information please contact your local Medtronic representative and/or consult the Medtronic website at [www.medtronic.eu](http://www.medtronic.eu).

For applicable products, consult instructions for use on [www.medtronic.com/manuals](http://www.medtronic.com/manuals). Manuals can be viewed using a current version of major internet browser. For best results, use Adobe Acrobat® Reader in the browser.

When ITB is mentioned, we are considering Intrathecal baclofen (an antispasmodic) administered by an intrathecal drug delivery pump therapy. Medtronic provides only the intrathecal drug delivery pump and the catheter; the baclofen is provided by an external company.

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